Exhibit A

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff,

v.

INTUITIVE SURGICAL, INC.,

Defendant.

Case No. 3:21-cv-03496-AMO

DEFENDANT'S MOTION FOR RECONSIDERATION OR, IN THE ALTERNATIVE, FOR CERTIFICATION OF AN INTERLOCUTORY APPEAL

Date:
Time:
Courtroom: 10

The Honorable Araceli Martínez-Olguín

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on such date as may be directed by the Court, Defendant Intuitive Surgical, Inc. ("Intuitive") will and hereby does move the Court, pursuant to Civil Local Rule 7-9 and Federal Rule of Civil Procedure 54(b), to reconsider portions of the Court's December 11, 2024 Order Re Motions *In Limine* (Dkt. 330, the "Order"). Intuitive requests that the Court reconsider its rulings granting Plaintiff Surgical Instrument Service Company, Inc.'s ("SIS") motions *in limine* #1 and #5 and imposing additional conditions with respect to Intuitive's motion *in limine* #4. Intuitive respectfully submits that reconsideration is warranted under Civil Local Rule 7-9(b)(3), Rule 54(b), and/or the inherent authority of the Court to prevent clear error or manifest injustice. In the alternative, Intuitive requests that the Court certify its Order for interlocutory appeal pursuant to 28 U.S.C. §1292(b) and stay proceedings pending the resolution of the request for an interlocutory appeal and any appellate proceedings.

This Motion is based upon this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities in support thereof, and such arguments and authorities as may be presented at or before the hearing.

STATEMENT OF THE ISSUES TO BE DECIDED

1. Whether the Court should reconsider the portion of its December 11, 2024 Order granting SIS's motions *in limine* #1 and #5 and excluding all evidence relating to the FDA's 510(k) clearance process.

2. Whether the Court should reconsider the portion of its December 11, 2024 Order imposing additional conditions with respect to Intuitive's motion *in limine* #4 such that Intuitive is prohibited from introducing evidence relating to events after November 2022.

3. If the Court denies leave to seek reconsideration or declines to reconsider the relevant portions of its December 11, 2024 Order, whether the Court should certify, pursuant to 28 U.S.C. § 1292(b), an interlocutory appeal as to the following questions of law: (i) whether the Court erred in excluding all evidence relating to the FDA 510(k) clearance process and (ii) whether

the Court erred in prohibiting Intuitive from introducing evidence relating to events after November 2022.

4. Whether the Court should stay proceedings pending the resolution of Intuitive's request for an interlocutory appeal and any appellate proceedings.

MEMORANDUM OF POINTS AND AUTHORITIES

PRELIMINARY STATEMENT

Intuitive respectfully requests that the Court reconsider the portions of its December 11, 2024 Order (Dkt. 330) granting SIS's motions *in limine* #1 and #5 and imposing additional conditions with respect to Intuitive's motion *in limine* #4. As this Court recognized, these motions raised "important" issues that will "significantly shape the presentation of evidence at trial." November 25, 2024, Hearing Tr. at 44:10–11, 106:22 ("Hearing"). Intuitive submits that the Court misapprehended the nature of the arguments and evidence at issue, and otherwise clearly erred, in excluding all evidence relating to the FDA's 510(k) clearance process and in prohibiting Intuitive from introducing evidence relating to events after November 2022. The Court should correct those errors now rather than conduct a lengthy trial based on an incomplete and misleading evidentiary record and wait for the Ninth Circuit to reverse (and order a retrial) on an appeal from a final judgment. In the alternative, Intuitive respectfully requests that the Court certify its rulings for an interlocutory appeal and stay proceedings pending appeal.

In its Order resolving the motions *in limine*, the Court committed two fundamental errors that warrant reconsideration under Civil Local Rule 7-9(b)(3). *First*, the Court misapprehended or failed to consider Intuitive's arguments and evidence and otherwise erred in broadly excluding all evidence related to the FDA's 510(k) clearance process on the grounds that such evidence is not relevant (under Federal Rules of Evidence 401 and 402) and is more prejudicial than probative (under Federal Rule of Evidence 403). The Court's ruling proceeded from the mistaken premise that evidence of FDA's 510(k) regulatory framework will be used as it might in a products liability case to prove that Intuitive's products are safe and SIS's services are unsafe. That is incorrect. While Intuitive maintains that the FDA's entire regulation of medical devices, including the 510(k) process, is concerned with safety—as numerous courts have found, FDA regulations demonstrate,

FDA has stated, and SIS's own FDA expert opined—Intuitive is not relying on evidence of the FDA's process or determinations to prove that any device is safe or unsafe. Rather, such evidence is relevant to many other issues in this case, including one that the Court identified as central—whether Intuitive engaged in anticompetitive conduct. And that is so because of what the Court agreed that the 510(k) clearance process *does* involve—namely, "inquiry into a new device's equivalence with an earlier-approved medical device." Dkt. 330, at 2.

Simply put, a key question for the jury is whether it was anticompetitive for Intuitive to adopt a contractual policy requiring surgical instruments and accessories "made or approved by Intuitive" and prohibiting unauthorized modifications as well as "repair, refurbishment or reconditioning not approved by Intuitive." To establish the reasonableness of that policy, Intuitive seeks to introduce evidence showing that it would approve third-party products and services, so long as they had been proven to be *equivalent to*—or, *as safe and effective as*—earlier-approved medical devices, including Intuitive's own original EndoWrists. Intuitive further seeks to introduce evidence showing that it offered to third parties two alternative routes of proving such equivalence—obtaining FDA clearance or submitting clinical proof to Intuitive. Yet SIS and its partner Rebotix did neither. The Court's blanket prohibition on FDA-related evidence, however, would prevent the jury from hearing and seeing key parts of that record, despite their relevance and clear probative value. There is no basis under the Federal Rules of Evidence to support such a ruling, and its effect will cause serious and irremediable prejudice to Intuitive at trial—tainting any verdict the jury might reach before opening statements even begin.

To demonstrate how integral FDA-related evidence is to this case, and how confusing to the jury and prejudicial to Intuitive it would be to exclude *all* such evidence, Intuitive is submitting with this motion a detailed proffer setting out the key evidence it proposes to introduce and describing the relevance of that evidence. *See* Decl. Of particular note, this includes evidence that SIS itself has identified as central to *its* case—such as Intuitive's letters to hospitals that used unauthorized third-party services. Those letters detail Intuitive's concerns about the use with Intuitive's systems of modified EndoWrists that have not been determined by the FDA (or by Intuitive) to be equivalent to Intuitive's original FDA-cleared EndoWrists, and the letters assert

Intuitive's belief that such unauthorized activities are both illegal and unsafe. SIS is going to talk to the jury about those letters, which it labels as "threats," in opening statements and throughout the trial. They are the centerpiece of SIS's case—conduct that SIS claims was a central cause of its alleged injury and damages. But it would be enormously prejudicial for SIS to be allowed to rely on those letters and ask the jury to base a verdict on them without the jury seeing and hearing about what the letters *actually say*. And a significant part of what the letters say is that Intuitive believes that the activities of unauthorized third parties who modify EndoWrists are in conflict with FDA regulations, fail to meet the rigorous product specifications established by Intuitive and cleared by the FDA, and have not been demonstrated to be safe *or equivalent* to Intuitive's FDA-cleared products. *See, e.g.*, Decl. ¶ 5. SIS has not explained how exactly it intends to introduce these letters without opening the door to all the same FDA issues its motion sought to exclude, but it is certainly no solution to say that the letters can be presented to the jury with all references to the FDA redacted out: how can the jury be asked to judge the reasonableness of Intuitive's conduct with customers if it is permitted to hear only *part* of what Intuitive actually said to its customers, or to hear only Intuitive's conclusion regarding the use of unauthorized third-party services without also hearing the reasons Intuitive actually gave to support that conclusion?

As Intuitive will show herein and in the accompanying proffer, the same applies to other key pieces of FDA-related evidence, which cannot be excluded from trial without effectively denying Intuitive the right to defend against SIS's claims. It is telling that SIS itself has identified as trial exhibits more than 200 documents that reference the FDA—roughly one third of the total number of trial exhibits on SIS's list.

To be clear, Intuitive (while preserving its appellate rights with respect to the Court's summary judgment rulings) will *not* argue to the jury that it should conclude that what SIS and other unauthorized third parties were doing *actually was illegal* under the Food, Drug, and Cosmetic Act ("FDCA"). Intuitive respectfully suggests that any doubt about that issue can be put to rest by the Court instructing the jury (again, subject to Intuitive preserving this issue for appeal) that to date the FDA has not reached a final determination as to whether 510(k) clearance is required for EndoWrist modification services of the kind that SIS offered and that the jury may

not base its verdict on a determination as to whether SIS was or was not legally required to obtain 510(k) clearance. Such an instruction will avoid any "mini-trial" on FDA-related legal issues.

But regardless of any legal requirement, Intuitive's beliefs about the significance of FDA clearance are indisputably a key part of the rationale behind its actions and must be considered in determining whether such actions violated the antitrust laws. The jury may ultimately decide that such actions were nevertheless anticompetitive, or that Intuitive's stated beliefs were a pretext (though Intuitive does not believe that such a finding would be supported by the evidence). But there is no basis to *preclude* the jury from even hearing about such beliefs—especially where this Court has made (and will make) no determination as to the legality of SIS's conduct, *one way or the other*, under the FDCA. Any other result would be tantamount to this Court making "a dispositive ruling on a claim" in favor of SIS, despite the fact that a motion *in limine* "is not the proper vehicle for seeking" such a ruling. Dkt. 330, at 1 (citation omitted).

Nor is the strong relevance and probative value of this evidence outweighed by any prejudicial effect. In holding otherwise, the Court relied on cases involving products-liability claims in which parties attempted to use the fact of 510(k) clearance to establish that a product was safe and not defective. But in doing so, the Court again misapprehended what Intuitive intends to argue at trial. Here, Intuitive does *not* seek to present FDA-related evidence to prove as a matter of fact that the original EndoWrists were safe or that modified EndoWrists were unsafe products. Dkt. 330, at 3. Instead, Intuitive seeks to present such evidence to establish (among other things) that it acted reasonably in using 510(k) clearance as a proxy for ensuring that modified products were *as safe as the originals* and that, in refusing to obtain such clearance—while nevertheless telling customers that it was restoring EndoWrists to Intuitive's original FDA-cleared specifications—SIS was not excluded from competition but instead simply chose not to compete. There is no reason to think that introducing FDA-related evidence for these and related purposes will confuse the jury or result in a "mini-trial" on the regulatory scheme. And there is certainly no reason to think that *all* FDA-related evidence must be excluded to avoid such issues. On the contrary, it will be immensely confusing and misleading for the jury to exclude all FDA-related evidence given that such evidence is inextricably intertwined with other key evidence in this case.

Second, the Court also misapprehended Intuitive's arguments and evidence and otherwise clearly erred in prohibiting Intuitive from introducing evidence relating to events after November 2022—in particular, the fact that in March 2023 Intuitive *did* approve under its contracts a third party who obtained FDA clearance. That fact is public and has been known to SIS for almost two years at this point. By ruling that Intuitive is barred from introducing post-2022 evidence, the Court effectively made another dispositive ruling in SIS's favor on an issue that is hotly contested. Specifically, SIS urged the Court to exclude post-2022 evidence as irrelevant because SIS claims that it had already been excluded from the market and foreclosed from competing by Intuitive before 2022. Intuitive vehemently disputes that claim. By granting SIS the evidentiary ruling it requested, the Court has essentially decided that SIS was in fact excluded after 2022, and has taken away from the jury the ability to make that factual determination for itself. Additionally, the Court has set up a record on which it may appear to the jury (whether SIS argues this or not) that Intuitive *never* actually authorized a third party that modifies EndoWrists, even though that is flatly untrue. Again, SIS is free to argue to the jury that Intuitive's actions were reasonable or unreasonable, procompetitive or anticompetitive, genuine or pretextual. The point is that the jury's determinations on those issue will be meaningless and prejudicial if it is not allowed to hear evidence concerning what Intuitive actually did and why.

Finally, and in the alternative, Intuitive respectfully requests that the Court certify its Order for an interlocutory appeal under 28 U.S.C. § 1292(b) and that it stay all proceedings pending resolution of that request and any appellate proceedings. As discussed herein, the Court's rulings, if not modified, will create significant and unavoidable problems with the presentation of evidence at trial, starting with opening statements on day one. Intuitive therefore respectfully requests that the Court address these issues now, either by reconsideration or by allowing its rulings to be considered by the Ninth Circuit.

RELEVANT BACKGROUND

On October 28, 2024, the parties filed three motions *in limine* as relevant to this proceeding. SIS filed two essentially repetitive motions (motions *in limine* #1 and #5) to exclude all evidence relating to the FDA 510(k) clearance process on the grounds that such evidence was not relevant

under Federal Rules of Evidence 401 and 402 and substantially more prejudicial than probative under Federal Rule of Evidence 403. Pl.'s motion *in limine* ("MIL") 1, Dkt. 298, at 6–7; Pl.'s MIL 5, Dkt. 300, at 5–6. In particular, SIS argued that the evidence was irrelevant because 510(k) clearance does not shed meaningful light on the safety of products and because this Court had previously held that the parties could not litigate whether SIS's services required FDA clearance. *See* Pl.'s MIL 1, Dkt. 298, at 6; Pl.'s MIL 5, Dkt. 300, at 5. Relying on products-liability cases, SIS also argued that the evidence was substantially more prejudicial than probative because it would likely confuse the jury about the significance of 510(k) clearance and would waste time. *See* Pl.'s MIL 1, Dkt. 298, at 6–7; Pl.'s MIL 5, Dkt. 300, at 5–6. Intuitive filed a motion (motion *in limine* #4) to prevent SIS from introducing evidence from after November 2022, other than the limited information that SIS provided in response to the Court's prior discovery order, on the ground that SIS should be estopped from doing so after opposing discovery on this issue. Def.'s MIL 4, Dkt. 294, at 4–5.

On November 7, 2024, the parties filed oppositions to the respective motions. In response to SIS's motions *in limine* #1 and #5, Intuitive explained that 510(k) clearance, although not dispositive of safety, was at least relevant to safety and that evidence related to the clearance process was relevant for numerous reasons apart from whether it established a product's safety or whether SIS's services were legally required to be cleared by the FDA. *See* Def.'s Opp. to MIL 1, Dkt. 298, at 1–6; Def.'s Opp. to MIL 5, Dkt. 300, at 1–6. Intuitive also argued that the products-liability cases cited by SIS were inapposite and that FDA-related evidence did not satisfy the high bar for exclusion under Rule 403. For its part, SIS did not oppose Intuitive's motion *in limine* #4 but requested that the Court also prohibit *Intuitive* from introducing evidence from after November 2022. *See* Pl.'s Opp. to MIL 4, Dkt. 294, at 1–2. SIS did not provide any support or legal authority for this request, relying instead on a bare and unexplained invocation of "fairness." *Id*. at 3.

On December 11, 2024, the Court granted all three motions and adopted SIS's request with respect to Intuitive's motion *in limine* #4. Dkt. 330. As for evidence relating to the FDA's 510(k) clearance process, the Court reasoned that the evidence should be excluded because 510(k) clearance does not involve "an inquiry into the safety of the new product" and because "any

probative value of the evidence . . . is greatly outweighed by the danger of, among other things, confusing the issues, misleading the jury, and wasting time." Dkt. 330, at 2–3 (internal quotation marks and citations omitted). The Court also reasoned that Intuitive was seeking "to relitigate the role the regulatory framework played in SIS's market participation," an issue that the Court stated it had "already resolved at summary judgment." *Id*. at 5–6. The Court believed that Intuitive was attempting "to enforce the FDCA through this case" by establishing that "SIS failed to obtain 510(k) clearance as if it was required." *Id*. at 6. As for evidence relating to events after November 2022, the Court stated that Intuitive had not established that "factual events taking place since the close of fact discovery should bear on either liability or damages calculations in antitrust cases." *Id*. at 8. In a footnote, the Court also noted that it would be "inequitable" to allow Intuitive to introduce such evidence if SIS was not allowed to do so. *Id*. at 5 n.2.

Intuitive's proffer submitted herewith identifies the key FDA-related and post-2022 evidence that Intuitive would seek to introduce at trial if not excluded by the Court's rulings.

LEGAL STANDARD

District courts have discretion to reconsider their own orders. *Gray* v. *Golden Gate Nat. Recreational Area*, 866 F.Supp.2d 1129, 1132 (N.D. Cal. 2011) (citation omitted). Under Civil Local Rule 7-9, parties can move for reconsideration by receiving leave from the court and showing at least one of three factors: (1) "[t]hat at the time of the motion for leave, a material difference in fact or law exists from that which was presented to the Court before entry of the interlocutory order for which reconsideration is sought"; (2) "[t]he emergence of new material facts or a change of law occurring after the time of such order"; or (3) "[a] manifest failure by the Court to consider material facts or dispositive legal arguments which were presented to the Court before such interlocutory order." Civ. L.R. 7-9(b); *see Gamevice, Inc.* v. *Nintendo Co., Ltd.*, 2023 WL 4032009, at *1 (N.D. Cal. June 14, 2023). Beyond those factors, district courts have "inherent authority" to reconsider prior orders so as to "prevent clear error or prevent manifest injustice." *Gray*, 866 F. Supp. 2d at 1132. And particularly relevant here, this Court has recognized that *in limine* "rulings are not binding on the trial judge, and the judge may always change [their] mind during the course of a trial." Dkt. 330, at 1 (citation and alteration omitted).

"An interlocutory appeal under 28 U.S.C. § 1292(b) is authorized when a district court order involves a controlling question of law as to which there is substantial ground for difference of opinion and where an immediate appeal from the order may materially advance the ultimate termination of the litigation." *Juliana* v. *United States*, 949 F.3d 1125, 1126 (9th Cir. 2018) (cleaned up) (citation omitted). "[A]ll that must be shown in order for a question to be 'controlling' is that resolution of the issue on appeal could materially affect the outcome of litigation in the district court." *In re Cement Antitrust Litig.*, 673 F.2d 1020, 1026 (9th Cir. 1981) (citation omitted), *aff'd sub nom. Arizona* v. *Ash Grove Cement Co.*, 459 U.S. 1190 (1983). "A substantial ground for difference of opinion exists where reasonable jurists might disagree on an issue's resolution[.]" *Reese* v. *B.P. Expl. (Alaska) Inc.*, 643 F.3d 681, 688 (9th Cir. 2011). The party seeking an interlocutory appeal need not show that it will "have a final, dispositive effect on the litigation" but only that it "may materially advance the litigation." *Id.* It suffices that the interlocutory appeal "may avoid protracted and expensive (but ultimately unnecessary) litigation and the burdens on the litigants and court system[.]" *Beeman* v. *Anthem Prescription Mgmt., Inc.*, 2007 WL 8433884, at *2 (C.D. Cal. Aug. 2, 2007).

ARGUMENT

I. THE COURT SHOULD RECONSIDER ITS DECISION EXCLUDING ALL EVIDENCE RELATED TO THE 510(K) CLEARANCE PROCESS.

In its motions *in limine* #1 and #5, SIS moved to exclude *all* evidence related to the FDA 510(k) clearance process both on the ground that it was not relevant under Federal Rules of Evidence 401 and 402 and on the ground that it was substantially more prejudicial than probative under Federal Rule of Evidence 403. *See* Pl.'s MIL 1, Dkt. 298, at 6–7; Pl.'s MIL 5, Dkt. 300, at 5–6. In granting those motions, the Court appeared to invoke both grounds asserted by SIS. *See* Dkt. 330, at 2–6. The Court should reconsider its ruling.

A. FDA-related evidence is relevant.

The Federal Rules of Evidence set a "low bar for relevance," *United States* v. *Holmes*, 2021 WL 2044470, at *7 (N.D. Cal. May 22, 2021), requiring merely that the evidence have "any tendency to make a fact more or less probable than it would be without the evidence" and that the

fact be "of consequence in determining the action," Fed. R. Evid. 401. Evidence related to the FDA's 510(k) clearance process is highly relevant to numerous issues at the heart of this case as set forth both below and in the attached proffer. *See* Decl. That has been true since the beginning of this litigation as demonstrated by the numerous references in SIS's own complaint to the FDA's clearance process and oversight of the products at issue. *See, e.g.*, Dkt. 1 ¶¶ 19, 25, 27, 33, 45, 54–55, 57, 68. Indeed, the Court itself recognized that "510(k) clearance is clearly relevant in the context of this case and how it has been litigated so far." Dkt. 330, at 3. But in issuing a blanket order excluding all this evidence, the Court misapprehended *how* the evidence was relevant.

First, FDA-related evidence is relevant to whether SIS can establish its tying and exclusive-dealing claims in the first place because it shows that Intuitive has approved—and will approve—any third parties that secure FDA clearance or otherwise demonstrate through clinical evidence that their modified EndoWrists meet the specifications of and are as safe and effective as Intuitive's original EndoWrists. *See* Decl. ¶¶ 28, 32–33.[1] Intuitive should not be precluded from offering this evidence to argue that SIS was not excluded from the market and instead simply chose not to seek contractual authorization to be a third-party provider following the criteria specified by Intuitive. *See Betaseed, Inc.* v. *U & I Inc.*, 681 F.2d 1203, 1224 (9th Cir. 1982); *Photovest Corp.* v. *Fotomat Corp.*, 606 F.2d 704, 722 (7th Cir. 1979); *see also* Def.'s Trial Br., Dkt. 279-1, at 6–9.

[1] Intuitive does not understand the Court's Order as generally precluding it from introducing evidence that Intuitive would *also* approve third parties that provided clinical evidence *to Intuitive* that their services are safe and effective, regardless of whether the party obtained FDA clearance. *See* Def.'s Trial Br., Dkt. 279-1, at 6 n.6; *see also* Dkt. 330, at 3, 5 (noting that Intuitive may introduce evidence about safety separate from the 510(k) clearance process). For example, both SIS and Intuitive have included on the exhibit list certain "cease and desist" letters to third parties (including Rebotix and Restore) in which Intuitive specifically requested that the third parties provide evidence *either* that they had obtained 510(k) clearance *or* that they were in possession of other clinical proof that their service "returns the modified instruments to a 'production equivalent qualification' and/or that additional use does not affect the safety or performance of the instruments." Decl. ¶¶ 4, 6. The third parties never responded to these letters by providing any such clinical proof in order to seek Intuitive's contractual authorization. For the reasons discussed in the main text, the Court should allow the admission of the *entire* letters. But, at a minimum, there is no basis in the Court's Order to exclude the letters in their entirety and in particular their references to the approval mechanisms separate and apart from the 510(k) clearance process, and Intuitive does not understand the Court's Order as requiring such exclusion.

Second, FDA-related evidence is relevant to whether Intuitive had legitimate business reasons for its contractual policies regarding unauthorized products and services under the rule-of-reason framework. For instance, the evidence supports the argument that Intuitive required third parties to secure FDA clearance or provide other clinical evidence of equivalence—that the modified EndoWrists exhibited the same safety and effectiveness as Intuitive's EndoWrists—to help ensure the reliability and safety of its products (and, as corollaries, to protect its reputation and brand), procompetitive justifications that this Court recognized in its summary judgment decision. *See* Dkt. 204, at 18; *see also* Decl. ¶¶ 4, 6, 28, 33; Def.'s Trial Br., Dkt. 279-1, at 9–10. The evidence also supports the argument that the failure of SIS and other unauthorized third parties to obtain FDA clearance at least raised reasonable doubts from Intuitive's perspective about whether the modified EndoWrists were substantially equivalent to the originals. *See* Decl. ¶¶ 4–7. And the evidence shows that at least some hospitals viewed FDA clearance as a proxy for safety—or otherwise placed value on FDA clearance such that they required or preferred to use only FDA-cleared medical devices in surgery—and therefore that Intuitive's policies were responsive to consumer demand. *See* Decl. ¶¶ 34–45; *Epic Games, Inc.* v. *Apple, Inc.*, 67 F.4th 946, 987 (9th Cir. 2023) (noting that goal of "tapping into consumer demand" was a "plainly procompetitive rationale[]").

Third, FDA-related evidence is relevant to whether SIS can establish causation and damages for its antitrust claims. For instance, evidence that FDA clearance was a significant factor in shaping the demand of at least some hospitals for modified EndoWrists, and that at least some hospitals that bought modified EndoWrists from Rebotix or Restore wrongly believed that those products *had* been cleared by the FDA, is relevant to the question of whether an alternative cause (lack of FDA clearance) impacted SIS's ability to compete. *See* Decl. ¶¶ 34–46; *see also* Hearing at 36:9–11 (the Court noting concern about "Intuitive's ability to argue that customers cared about the clearance and, thus, SIS's failure to obtain it impacts antitrust causation and damages"). Likewise, evidence that SIS did not seek approval from Intuitive—by obtaining FDA clearance or otherwise—is also relevant to SIS's alleged damages. *See* Decl. ¶¶ 24–27.

Fourth, FDA-related evidence is relevant to the credibility of SIS's witnesses. For instance, SIS's executives testified that Rebotix had applied for FDA clearance but did not know whether Rebotix had been granted clearance even though they repeatedly told customers that the device had been proven to be safe, effective, and equivalent in specifications to Intuitive's original, FDA-cleared EndoWrists. *See* Decl. ¶¶ 14, 24–27. Intuitive is entitled to cross-examine those witnesses on issues that go to their credibility. *See, e.g.*, *Palantir Techs. Inc.* v. *Abramowitz*, 639 F. Supp. 3d 981, 986–87 (N.D. Cal. 2022).

Fifth, FDA-related evidence is relevant to Intuitive's counterclaims that SIS lied or misled customers when it represented that its modified EndoWrists were equivalent in specifications to the originals. The FDA's deficiency letter to Rebotix in 2015, however, pointed out specifically that Rebotix had failed to prove such equivalence and that it did "not seem possible" to prove such equivalence based on the kinds of information and testing that Rebotix had identified. Decl. ¶ 15. Such evidence—along with evidence that SIS did not disclose to customers that the modified EndoWrists it was offering had failed to gain FDA clearance—is relevant to proving that SIS's statements to customers were false and misleading. *See* Decl. ¶ 14.

The Court excluded *all* of this highly probative evidence on grounds that are not supported by law or the record.

1. The relevance and probative value of the FDA-related evidence does not depend on whether 510(k) clearance was legally required.

The Court reasoned that Intuitive was seeking "to relitigate the role the regulatory framework played in SIS's market participation" and "to enforce the FDCA" by showing that "SIS failed to obtain 510(k) clearance as if it was required." Dkt. 330, at 5–6 & n.1. Respectfully, the Court was mistaken. For instance, evidence that Intuitive offered a non-illusory approval process (which it not only made available to third parties but *actually applied* to approve at least one third party that met its criteria), that its policies with regard to approval and the use of unauthorized third-party products and services with Intuitive systems were reasonable, and that SIS unreasonably failed to seek approval from Intuitive or to seek FDA clearance is all relevant to this case regardless of whether SIS's services legally *required* clearance from the FDA or whether

SIS violated the FDCA. After all, private companies may take reasonable measures to ensure the safety and efficacy of their products even if those measures are not technically required by law. *Cf. Novartis Pharms. Corp.* v. *Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024) (noting that regulatory "silence implies that [companies] may impose distribution conditions by contract, not that they are prohibited from doing so").[2] And that is particularly so when the company has good reasons to think that those measures *are* legally required, as Intuitive did here. That would be true even if it turned out that Intuitive was wrong about the application of FDA regulations to SIS's services—though here, the FDA has never reached that conclusion, and the Court expressly declined to reach that conclusion at summary judgment. Dkt. 204, at 12–13.

Likewise, evidence that the FDA identified substantial deficiencies in Rebotix's application for clearance of its modified EndoWrists is relevant to the reasonableness of Intuitive's decision not to treat those modified EndoWrists as authorized under its contracts, as well as to whether SIS misrepresented that its products were equivalent to the original EndoWrists. Decl. ¶¶ 14–23. Again, the relevance of such evidence does not turn on whether Rebotix was required to seek FDA clearance in the first place. For starters, the fact that Rebotix *chose* to seek FDA clearance (as other third parties have done) is relevant on its own to establishing the *competitive* significance of such clearance in this marketplace. Specifically, it tends to reflect that hospital customers prefer (if not require) the use of products and services that are cleared by the FDA, and tends to undercut SIS's claim that there would be significant customer demand for an EndoWrist modification service *not* cleared by the FDA. As another third-party witness put it, FDA clearance, from a marketing perspective, is like the "Good Housekeeping seal of approval." Decl. ¶ 42.

In addition, the FDA's reasons for rejecting Rebotix's application highlight why it was so reasonable for Intuitive to consider FDA clearance as part of its authorization policy (and so

[2] Even assuming that Intuitive has no standing to enforce the FDCA, that does not preclude Intuitive from asking third parties to obtain FDA approval as one path to obtaining Intuitive's *contractual* authorization. Private parties frequently reference FDA approval as a *contractual* condition to the sale of products regulated by the FDA. *See*, *e.g.*, *Helsinn Healthcare S.A.* v. *Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1362 (Fed. Cir. 2017). To our knowledge, no court has ever suggested that contractual provisions regarding FDA approval amount to inappropriate enforcement of the FDCA by private parties.

misleading for SIS to represent that its modified EndoWrists were equivalent in specifications to the originals). In particular, the FDA found that Rebotix had failed to demonstrate that it had any sound or reliable basis for claiming that its EndoWrist modification process returned Intuitive's products to their original or "OEM-equivalent specifications." Decl. ¶ 19. It is not difficult to understand why, in these circumstances, Intuitive would have concerns about an unauthorized third party performing modifications to a product that *Intuitive* invented and bears *Intuitive's* brand name. The unauthorized third party—here, Rebotix or SIS—would be reselling that modified product back to *Intuitive's* customers for use with *Intuitive's* surgical systems, even though it had failed to demonstrate to the FDA, or to Intuitive, that its modified product was *at least equivalent to the one Intuitive had manufactured*. In short, such evidence tends to validate Intuitive's policies as a reasonable precaution against the possibility that unauthorized third parties would free ride on Intuitive's brand name, reputation for quality, and goodwill, by offering an inferior (albeit cheaper) version of Intuitive's own product—all while potentially putting the safety of patients at risk. At a minimum, the jury should be allowed to take this evidence into account in determining whether Intuitive acted reasonably with respect to SIS as a reseller of Rebotix's unauthorized product.

2. The issues presented by SIS's motions *in limine* were not presented or resolved at summary judgment.

The Court also misapprehended Intuitive's arguments and evidence in stating that it had "already resolved" these issues "at summary judgment." Dkt. 330, at 5. In its summary judgment decision, the Court held that neither party could raise claims or arguments insofar as they would entail deciding "whether Section 510(k) clearance was required" because that "would constitute private enforcement of the FDCA." Dkt. 204, at 15. But as just explained, Intuitive is *not* seeking to introduce FDA-related evidence to show that 510(k) clearance "was required" or to enforce a violation of the FDCA. Nor is there any basis or authority for expanding the Court's narrow summary judgment decision into a blanket rule of evidentiary exclusion. Indeed, on the same day as its summary judgment decision, the Court concluded that one of SIS's experts could testify about "FDA's practices and procedures as well as how such practices and procedures influence the parties' arguments regarding the Section 510(k) regulatory frame" because such evidence "will

aid the fact finder." Dkt. 203, at 20–21. The parties have been preparing this case for trial on that basis, and that conclusion would make no sense if the Court had already decided that all evidence about the FDA clearance process was wholly irrelevant to this case.

In any event, as noted above, Intuitive is willing to eliminate any remaining doubt about whether it is trying to revisit the Court's summary judgment rulings or argue to the jury that FDA clearance was legally required by agreeing (subject to preservation of all appellate rights) to a jury instruction that states, tracking the language of the Court's summary judgment decision, that FDA has taken no final position on whether 510(k) clearance is required for SIS's EndoWrist services and that the jury may not base its verdict on a determination as to whether SIS was or was not legally required to obtain 510(k) clearance. Dkt. 204, at 12–13.

3. FDA-related evidence is not irrelevant to safety in the context of this antitrust case.

In addition, the Court appears to have believed that evidence relating to the 510(k) clearance process should be excluded because it is irrelevant to safety. Dkt. 330, at 2–3, 5–6. As an initial matter, although the 510(k) clearance process may not definitively resolve whether a product is safe, that is far different from saying that the process is *irrelevant* to product safety. Both courts and the FDA itself have recognized that the 510(k) process sheds light on the safety and effectiveness of a product. *See, e.g.*, *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 493 (1996) (noting that although the "510(k) process is *focused* on equivalence, not safety," "the FDA may well examine § 510(k) applications . . . with a concern for the safety and effectiveness of the device" (citation omitted; emphasis altered)); *In re Cook Med., Inc., IVC Filters Mktg., Sales Pracs. & Prod. Liab. Litig.*, 2018 WL 6617375, at *1 (S.D. Ind. Dec. 18, 2018); *Otero* v. *Zeltiq Aesthetics, Inc.*, 2018 WL 3012942, at *3 (C.D. Cal. June 11, 2018); 21 C.F.R. § 807.3(o) (defining a "510(k) summary" as "the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence can be based"); *id.* §§ 807.92(a)(5), (b)(2), 807.93(a)(1) (requiring 510(k) submissions to include certain evidence of

safety and effectiveness); Decl. ¶¶ 48–52.[3] And SIS's *own witnesses*, including SIS's *FDA expert*, have recognized the same point. *See* Decl. ¶¶ 43–45. This Court has previously declined "to step into the FDA's shoes" with respect to the regulatory clearance process. Dkt 204, at 13. But in excluding all FDA-related evidence, the Court did exactly that, determining—as a matter of law and contrary to the views of the FDA—that 510(k) clearance says nothing about safety.

The Court's ruling was particularly erroneous in this case where the issue is not whether the modified EndoWrists are "safe" in some abstract sense but rather whether Intuitive could conclude that they were not *as safe* as the original EndoWrists—that is, equivalently safe. Even on the Court's own understanding of the 510(k) clearance process, FDA-related evidence is relevant to that issue. *See* Dkt. 330, at 2 (noting that the "510(k) clearance involves an inquiry into a new device's equivalence with an earlier-approved medical device"). This includes, for example, the FDA's deficiency letter to Rebotix discussed above, which is relevant, among other reasons, precisely for what it has to say about Rebotix's failure to establish that its process for modifying EndoWrists restores them to "OEM-equivalent specifications"—and which is contrary to the claims that SIS made to customers on this very subject of equivalence to Intuitive's specifications. Decl. ¶¶ 14, 19. Of course, SIS is entitled to dispute at trial the extent to which the 510(k) clearance process is relevant to its claims and to argue that Intuitive did not require such clearance based on legitimate safety or quality concerns. But it would be error for the Court to resolve those disputed issues in a pretrial evidentiary ruling. *See, e.g.*, *Miranda* v. *U.S. Sec.*

[3] FDA, *Premarket Notification 510(k)* (current as of Aug. 22, 2024), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k ("A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device"); FDA, *Medical Device Safety and the 510(k) Clearance Process* (current as of Sept. 6, 2023), https://www.fda.gov/medical-devices/510k-clearances/medical-device-safety-and-510k-clearance-process ("Regardless of the type of regulatory pathway – PMA, De Novo, or 510(k) – the principles of safety and effectiveness underlie the FDA's review of all medical devices. . . . The information provided in a 510(k) submission is necessary for the FDA to determine substantial equivalence and to assure the safety and effectiveness of medical devices."); FDA, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510k]* 6 (July 28, 2014), available at https://www.fda.gov/media/82395/download ("the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review").

Assocs., Inc., 2019 WL 2929966, at *5 (N.D. Cal. July 8, 2019) (noting that "courts must be careful not to use [motions *in limine*] to resolve factual disputes or to weigh evidence" (citation omitted)).

Moreover, even assuming that the 510(k) clearance process does not shed any light on a product's safety, FDA-related evidence would still be relevant to numerous issues in the case, such as whether Intuitive had a non-illusory approval process, whether Intuitive and hospitals reasonably (but mistakenly) viewed the clearance process as a proxy for safety, and whether SIS's own executives viewed the clearance process as relevant to safety but failed to determine whether Rebotix had FDA clearance and failed to seek clearance themselves. Those issues are relevant regardless of whether the clearance process is *actually* a reasonable proxy for safety.

In excluding all FDA-related evidence, the Court effectively issued dispositive rulings that, as a matter of law, Intuitive lacked a non-illusory approval process based on 510(k) clearance and that Intuitive had no legitimate basis for using 510(k) clearance as a proxy for ensuring that modified products were as safe and effective as the originals. Such rulings are not only legally erroneous but procedurally improper. As the Court itself recognized, a motion *in limine* "is not the proper vehicle for seeking a dispositive ruling on a claim, particularly after the deadline for filing such motions has passed." Dkt. 330, at 1 (citation omitted).

For all those reasons, FDA-related evidence is not merely relevant but central to this case. At a minimum, the Court should reconsider its decision to issue a "blanket ruling" excluding all such evidence. *Sherwin-Williams Co.* v. *JB Collision Servs., Inc.*, 2015 WL 11237466, at *5 (S.D. Cal. Nov. 6, 2015); *see also U.S.A.* v. *Jackson*, 2016 WL 4059615, at *2 (C.D. Cal. July 25, 2016) ("motions *in limine* should rarely seek to exclude broad categories of evidence, as the court is almost always better situated to rule on evidentiary issues in their factual context during trial").

B. FDA-related evidence is not substantially more prejudicial than probative.

Federal Rule of Evidence 403 sets a "high bar" for excluding evidence as more prejudicial than probative: "a court may exclude relevant evidence only if its probative value is *substantially* outweighed by one or more of the articulated dangers or considerations." *Sidibe* v. *Sutter Health*, 103 F.4th 675, 691 (9th Cir. 2024). As the Ninth Circuit has explained, courts should be "cautious and sparing" when excluding evidence on this ground "because its major function is limited to

excluding matter of scant or cumulative probative force, dragged in by the heels for the sake of its prejudicial effect." *Id*. (internal quotation marks and citation omitted). The objecting party thus bears a "significant burden because exclusion under Rule 403 is an extraordinary remedy." *Munoz* v. *PHH Mortg. Corp.*, 2022 WL 138670, at *2 (E.D. Cal. Jan. 14, 2022) (internal quotation marks and citation omitted). The Court's misunderstanding of why FDA-related evidence is so highly probative in this case resulted in its erroneous conclusion that the evidence is substantially more prejudicial than probative.

Citing cases involving products-liability claims, the Court primarily expressed concern that FDA-related evidence would risk "confusing the jury" by leading it "to erroneously conclude that regulatory compliance proved safety." Dkt. 330, at 3 (quoting *In re C. R. Bard, Inc.*, 810 F.3d 913, 922 (4th Cir. 2016)); *Carter* v. *Johnson & Johnson*, 2022 WL 4700549, at *2 (D. Nev. Sept. 29, 2022); *Kaiser* v. *Johnson & Johnson*, 2018 WL 1358407, at *4 (N.D. Ind. Mar. 16, 2018), *aff'd,* 947 F.3d 996 (7th Cir. 2020). In some products-liability cases, courts have excluded evidence relating to the 510(k) clearance process where a party sought to use such evidence to establish that a product was safe and not defective. *See In re C. R. Bard, Inc.*, 810 F.3d at 920; *Kaiser*, 2018 WL 1358407, at *1; *Carter*, 2022 WL 4700549, at *2.[4] But contrary to the Court's assertion, Intuitive does *not* seek to present evidence of the 510(k) clearance process to prove as a matter of fact that SIS's modified EndoWrists are unsafe. *See* Dkt. 330, at 3. Instead, as explained above, Intuitive seeks to present such evidence to establish (among other things) that it acted reasonably under the antitrust laws in requiring evidence of 510(k) clearance from third parties in the absence of other clinical evidence of safety and effectiveness; that SIS was not excluded from competition as a result of the alleged anticompetitive conduct; and that SIS made false and misleading statements that its modified EndoWrists were equivalent to Intuitive's original EndoWrists in specifications and quality. *See* pp. 10–12, *supra*. Unlike in the products-liability

[4] Even in the products-liability context, courts have divided over whether evidence regarding the 510(k) clearance process is substantially more prejudicial than probative, with many holding it is not. *See, e.g.*, *In re Cook Med., Inc., IVC Filters Mktg., Sales Pracs. & Prod. Liab. Litig.*, 2018 WL 6617375, at *1–2 (S.D. Ind. Dec. 18, 2018) (collecting cases); *In re Bard IVC Filters Prod. Liab. Litig.*, 2018 WL 11445485, at *3–4 (D. Ariz. Jan. 29, 2018).

cases, that evidence is highly probative *regardless* of whether the 510(k) process says anything about safety. The evidence is not "ancillary to the gravamen of the claims at issue." Dkt. 330, at 4. Instead, it goes to the heart of "whether Intuitive engaged in anticompetitive conduct," as well as other elements of the parties' claims. Dkt. 330, at 4.

Indeed, the Court's ruling is particularly erroneous because excluding all evidence regarding the 510(k) process will itself "confus[e] the jury" because "[m]any of the relevant events in this case occurred in the context of FDA 510(k) review, and much of the evidence is best understood in that context." *In re Bard IVC Filters Prod. Liab. Litig.*, 2018 WL 11445485, at *4 (D. Ariz. Jan. 29, 2018). For instance, Intuitive understands that SIS plans to introduce cease-and-desist letters to show that Intuitive excluded it from the market, but those very same letters discuss the 510(k) clearance process at length, including the fact that Intuitive will approve third-party services that have received FDA clearance. *See* Decl. ¶¶ 4–6. There is no way to introduce redacted versions of that and other evidence without creating "a misleading, incomplete, and confusing picture for the jury." *Bard IVC Filters Prod. Liab. Litig.*, 2018 WL 11445485, at *4.

Likewise SIS has argued and will argue that the ten-use limit on EndoWrists is "arbitrary." Decl. ¶ 8. Yet it is undisputed that the FDA only cleared EndoWrists for a limited number of uses (initially ten for most EndoWrist instruments). Decl. ¶¶ 8–11. Furthermore, when Intuitive proposed to extend the use limits on newer-generation EndoWrists, the FDA required Intuitive to apply for a new 510(k) clearance. Decl. ¶ 12. SIS is free to, and clearly intends to, debate the validity of the EndoWrist use limits and to try to prove that EndoWrists can safely be used more times than the FDA cleared them to be used. But it is indisputable that the use limits are part of the FDA-cleared labeling for the EndoWrist product. And that is a clearly relevant fact of which the jury should be informed. It would be prejudicial and confusing for the jury to remain in the dark about that fact and not to be informed of it.

As yet another example, SIS attacks the enhanced encryption that Intuitive added to its X/Xi EndoWrists as being anticompetitive and not a genuine product improvement under *Allied Orthopedic Appliances Inc.* v. *Tyco Health Care Grp. LP*, 592 F.3d 991 (9th Cir. 2010). But Intuitive adopted that enhanced encryption technology in response to specific feedback it had

received from the FDA. In connection with seeking FDA clearance for its Xi da Vinci system, the FDA specifically required Intuitive to provide information to "address the safety and efficacy concerns involving the wireless technology" included in that system, and in particular to address concerns related to "data security." Decl. ¶¶ 50, 52. Intuitive reported to FDA in 2013 that the mitigation measures it undertook to address "critical" cybersecurity risks included encrypting the data on the RFID chip itself as well as the wireless communications between the chip and the da Vinci. Decl. ¶¶ 50–51. To the extent the Court's order prevents Intuitive from offering this FDA-related evidence, it would prohibit Intuitive witnesses from explaining the reasons for the encryption, forcing them to testify incompletely and therefore not fully truthfully, and further prejudicing Intuitive at trial.

The Court also expressed concerns that evidence about the 510(k) clearance process would "wast[e] time" and result in a "mini-trial." Dkt. 330, at 3–4 (internal quotation marks and citation omitted). But this Court has ordered time limits for the trial and made clear that it will not extend the time for trial. *See* Hearing at 5:13–19, 8:8–9. Those "time limits will avoid any risk of unnecessary or time-consuming mini-trials," and the Court should have "confiden[ce] that counsel for each side will be able to adequately and efficiently try this case in the time allotted by the Court." *Bard IVC Filters Prod. Liab. Litig.*, 2018 WL 11445485, at *4. That is particularly true in light of the jury instructions proposed by Intuitive above. *See id.*; pp. 15, *supra*.

Finally and more generally, the Court failed to explain how *every* piece of evidence related to the 510(k) process would result in extended and confusing proceedings about the clearance process. For instance, that Intuitive had a policy of approving third parties who obtained FDA clearance and that Intuitive in fact approved a third party who obtained FDA clearance is relevant to whether Intuitive had a non-illusory approval process regardless of the regulatory details of the clearance process. And even assuming that this evidence would require some "contextualizing" for the jury, the Court never explained how that basic context would automatically lead to a "sideshow likely to distract and confuse the jury." Dkt. 330, at 4–5.

For all those reasons, the FDA-related evidence in this case is not substantially more prejudicial than probative. At a minimum, the Court should decline to issue a "blanket ruling" on

the issue and should consider the particular evidence in context at trial. *Sherwin-Williams*, 2015 WL 11237466, at *5; *see also Biomet M2a Magnum Hip Implant Prod. Liab. Litig.*, 2017 WL 10845178, at *7 (N.D. Ind. Dec. 21, 2017) (declining to resolve whether FDA-related evidence was more prejudicial than probative because such a determination would be "premature").

II. THE COURT SHOULD RECONSIDER ITS DECISION PROHIBITING INTUITIVE FROM INTRODUCING EVIDENCE FROM AFTER NOVEMBER 2022.

In its Order on Intuitive's motion, the Court granted SIS's request to prohibit *Intuitive* from introducing any evidence from after November 2022 outside of the limited information that SIS provided in response to the Court's prior discovery order. In doing so, the Court did not explain the basis for excluding such evidence, other than noting that Intuitive had not shown that "factual events taking place since the close of fact discovery should bear on either liability or damages calculations in antitrust cases." Dkt. 330, at 8. Earlier in its decision, the Court also noted that it would exclude evidence that Intuitive had publicly announced that it will approve any third parties that secure FDA clearance because, in the Court's view, admitting such evidence would be "inequitable" in light of the Court's ruling prohibiting SIS from admitting evidence from after November 2022. *Id*. at 5 n.2. In issuing this decision, the Court again misapprehended the relevance of this evidence and otherwise clearly erred.

Federal Rule of Evidence 402 provides that "[r]elevant evidence is admissible" unless the U.S. Constitution, a federal statute, the Federal Rules of Evidence, or other rule provide otherwise. In other words, Rule 402 states the "broad principle" that relevant evidence should be admitted unless its admission would be contrary to one of those identified legal authorities. *Huddleston* v. *United States*, 485 U.S. 681, 687 (1988). Here, the Court did not (and could not) say that evidence from after November 2022 was wholly *irrelevant* to this case. As explained above, evidence that Intuitive had approved and would approve third parties is highly relevant to whether SIS can establish its tying and exclusive dealing claims in the first place, because it shows that Intuitive's approval process was anything but illusory. *See, e.g.*, pp. 10, 16-17, 20, *supra*. Likewise, evidence

from after November 2022 is highly relevant to the question of whether SIS could have competed but chose not to—an issue relevant to liability and damages. *See* Decl. ¶¶ 27, 28–33, 46.

At the Hearing, the Court suggested that evidence from after November 2022 may be irrelevant because damages should be calculated in the "but-for world." Hearing at 66:4–7. Even assuming that such evidence is not relevant to the question of damages, it would still be highly relevant to Intuitive's liability because it would show that Intuitive *had* approved a third party that modifies EndoWrists after the party obtained FDA clearance and thus had a non-illusory clearance process. Under the Court's Order, however, it may appear to the jury (whether SIS argues this or not) that Intuitive had never authorized a third party even though that is simply not true.

Moreover, real-world evidence from after November 2022 *is* relevant to determining damages in the but-for world. As one court in this circuit has explained, a "jury must be able to consider what actually occurred in the real world when evaluating the 'but-for world' and determining what would have happened if [the defendant] had not engaged in [the relevant unlawful] activities." *ICTSI Oregon, Inc.* v. *Int'l Longshore & Warehouse Union*, 2022 WL 16924139, at *9 (D. Or. Nov. 14, 2022). That is because the "but-for world" "requires consideration of actual real world conditions during the entire damages period, with the only fantastical element being that the unlawful conduct did not occur." *Id.*; *see, e.g.*, *In re Pool Prods. Distrib. Mkt. Antitrust Litig.*, 166 F. Supp. 3d 654, 678 (E.D. La. 2016). Here, the real world conditions include the fact that if SIS had sought and obtained FDA clearance or provided other clinical evidence of safety and effectiveness, then Intuitive would have approved it to modify EndoWrists. In addition, although SIS claims that it was driven out of business, Intuitive disputes that point and will offer evidence that SIS *chose* to stop competing in furtherance of this litigation. Decl. ¶ 24–27. The Court has not explained how this and other evidence from after November 2022 is irrelevant to the calculation of damages in the but-for world and it certainly cannot resolve these factual disputes in a pretrial evidentiary ruling. *See Miranda*, 2019 WL 2929966, at *5.

Nor has the Court identified any other legal basis for prohibiting Intuitive from introducing evidence from after November 2022. At most, the Court asserted that it would be "inequitable" to prevent SIS from introducing such evidence while allowing Intuitive to do so. Dkt. 330, at 5 n.2.

But the Federal Rules of Evidence do not contain any provision allowing courts to exclude evidence based on freestanding notions of fairness. And there is nothing inequitable in estopping SIS—and only SIS—from introducing such evidence based on its prior choice to block further discovery in this case. Indeed, it is the Court's Order that creates a fundamental inequity (and legal error) by allowing SIS to seek $170 million in damages up through 2026, while prohibiting Intuitive from obtaining discovery and presenting evidence from that time period.

III. TO AVOID A VERDICT TAINTED BY LEGAL ERROR AND UNCURABLE PREJUDICE TO INTUITIVE, THE COURT SHOULD VACATE ITS ORDER AND MAKE CLEAR THAT CERTAIN FDA-RELATED AND POST-2022 EVIDENCE IS ADMISSIBLE BEFORE OPENING STATEMENTS.

For all the reasons set out above, if the Court's order is left in place it will infect the trial with clear legal error and cause prejudice to Intuitive that cannot be undone before a verdict is rendered. Intuitive respectfully suggests that the Court can mitigate this result, and the near certainty of reversal by the Ninth Circuit, by taking certain concrete steps before the trial begins.[5]

First, the Court should vacate its blanket order with respect to FDA-related evidence. There is simply no basis to exclude all such evidence in advance of trial, and as discussed, doing so will cause confusion and prejudice from the very start of the case—for example, the first time that SIS mentions Intuitive's "threat" letters to customers without mentioning that those letters were in large part concerned with issues relating to FDA clearance.

Second, the Court should adopt a preliminary jury instruction along the lines Intuitive has proposed above, to clarify the purposes for which FDA-related evidence is and is not being offered and to avoid any possible confusion regarding whether the jury will be asked to determine whether FDA clearance was or was not required by law.

Third, while Intuitive believes that all of the evidence set out in its proffer is relevant and should ultimately be admitted at trial for the reasons set forth, the Court need not make a blanket ruling of admissibility right now, just as the Court should not adhere to its blanket ruling of inadmissibility. So that the basic parameters of the trial are clear, however, and so that the parties

[5] Intuitive respectfully disagrees with all aspects of the Court's adverse evidentiary rulings and preserves its rights to challenge those rulings on appeal. But for purposes of this motion, Intuitive has focused on the most critical errors in the Court's rulings.

can plan their opening statements accordingly, the Court should determine that the parties are not precluded from referencing at least the following kinds of evidence covered by its current rulings:

- Evidence that Intuitive's products, including EndoWrists, were cleared by the FDA for certain kinds of surgical procedures. Decl. ¶¶ 8–13.
- Evidence that the use limits for EndoWrists, along with testing supporting those use limits, were submitted to the FDA and reviewed as part of the FDA's clearance process. Decl. ¶¶ 8–13.
- Evidence that Rebotix applied for FDA clearance to modify EndoWrists, and received a deficiency letter from the FDA, after which Rebotix withdrew its application for clearance. Decl. ¶¶ 14–23.
- Evidence that SIS never applied for FDA clearance, and evidence regarding SIS's knowledge or lack thereof of the Rebotix deficiency letter. Decl. ¶¶ 24–27.
- Evidence that Intuitive expressed its concerns about the use and sale of modified EndoWrists by unauthorized third parties that lacked FDA clearance in letters to customers and to the third parties themselves. Decl. ¶¶ 4–7.
- Evidence that another third party, Iconocare, applied for and was granted FDA clearance for a particular modified EndoWrist. Decl. ¶¶ 28–32.
- Evidence that Intuitive made an announcement in March 2023 that its customers were free to purchase FDA-cleared modified EndoWrists without consequence under Intuitive's contracts. Decl. ¶ 33.

IV. IN THE ALTERNATIVE, THE COURT SHOULD CERTIFY THESE MATTERS FOR AN INTERLOCUTORY APPEAL UNDER 1292(B) AND STAY PROCEEDINGS PENDING APPEAL.

If the Court denies reconsideration, and declines to allow the kinds of evidence outlined above, Intuitive respectfully submits that the Court should certify its Order for interlocutory appeal because each of the requirements for certification under 28 U.S.C. § 1292(b) is met. *First*, the Order involves "controlling question[s] of law" because the Court's legal errors in analyzing the relevance and potential prejudice of the evidence at issue will "materially affect the outcome of

the litigation in the district court." *In re Cement*, 673 F.2d at 1026; *see also Am. Fed'n of Musicians of U.S. & Can.* v. *Paramount Pictures Corp.*, 903 F.3d 968, 975 (9th Cir. 2018) ("exclusion was legal error and therefore an abuse of discretion"). Those errors are on the face of the parties' briefing and record, and the Ninth Circuit will not need to delve into the record to resolve them. *Second*, for the reasons explained above, the Court clearly erred in excluding the evidence at issue, but at the very least, there is a "substantial ground for difference of opinion" because "reasonable jurists might disagree on [their] resolution." *Reese*, 643 F.3d at 688. *Finally*, an interlocutory appeal will "materially advance the ultimate termination of the litigation" by preventing this case from proceeding to trial on the basis of clearly erroneous evidentiary rulings, and thus avoiding the need for a re-trial after appeal. *See Beeman*, 2007 WL 8433884, at *2.

Intuitive also requests that the Court stay all proceedings pending the resolution of its request for an interlocutory appeal and any appellate proceedings because the balance of hardships and the orderly course of justice favor a stay. *See, e.g.*, *Kuang* v. *U.S. Dep't of Def.*, 2019 WL 1597495, at *2–4 (N.D. Cal. Apr. 15, 2019). No party will be significantly prejudiced by a stay, and both the parties and this Court will benefit from staying the lengthy forthcoming trial proceedings pending further guidance from the Ninth Circuit on these "important" issues that will "significantly shape the presentation of evidence at trial." Hearing at 44:10–11, 106:22; *see also Ottesen* v. *Hi-Tech Pharms., Inc.*, 2024 WL 589089, at *4 (N.D. Cal. Feb. 13, 2024); *Gustavson* v. *Mars, Inc.*, 2014 WL 6986421, at *3 (N.D. Cal. Dec. 10, 2014). For the same reasons, the orderly course of justice favors a stay because the interlocutory appeal may "significantly reshape the merits" of the case. *Kuang*, 2019 WL 1597495, at *6. Simply put, there is no reason to conduct an entire trial while critical evidentiary rulings remain in doubt.

CONCLUSION

For the foregoing reasons, Intuitive respectfully requests that the Court reconsider its rulings granting SIS's motions *in limine* #1 and #5 and imposing additional conditions with respect to Intuitive's motion *in limine* #4. In the alternative, Intuitive respectfully requests that the Court certify these rulings for an interlocutory appeal pursuant to 28 U.S.C. § 1292(b) and stay proceedings pending appeal.

Dated: December 16, 2024

By: /s/ *Kenneth A. Gallo*
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